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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/642,068

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John R. Stuelpnagel

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EXAMINER

STRZELECKA, TERESA E

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 12/02/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/642,068

Applicant(s)

STUELPNAGEL ET AL.

Examiner

Teresa E Strzelecka

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-10 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☒ Claim(s) 2-10 and 27-31 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This office action is in response to an amendment filed on August 7, 2003. Claims 2-10 and 27-32 were previously pending. Applicants cancelled claim 32, amended claims 2, 7 and 29.
2. Applicants' amendments and claim cancellations overcame objections to claims 2, 7, 8, 31 and 32 and rejection of claims 2-6, 9, 10 and 29 under 35 U.S.C. 112, second paragraph.
3. This office action is made non-final because of new grounds for rejection for claims 2-10 and 27-31.

Claim interpretation

4. The following interpretation of claim limitations is used to evaluate correspondence between the current claims and prior art:

A) The term "first and second linkers" is interpreted as linkers which may be the same, as there is no requirement that they have to be different.

B) The term "chip" in claim 29 is interpreted as any substrate (it is used interchangeably with "substrate" in the claim).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 27, 30, 31, 3-6 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Beattie (U.S. Patent No. 6,156,502).

Regarding claims 27 and 30, Beattie teaches a method for detection of nucleic acids, the method comprising:

a) providing a substrate and at least first and second different oligonucleotides linked to said substrate through first and second cleavable linkers, respectively (Beattie teaches providing a controlled pore glass support with a set of oligonucleotide probes linked to the substrate via 3'-amino linker (col. 8, lines 30-36; col. 12, lines 60-62; col. 16, lines 39-42).);

b) cleaving said first and second linkers, thereby releasing said first and second oligonucleotides from said substrate, thereby generating a pool of oligonucleotides comprising said first and second oligonucleotides (Beattie teaches cleaving the oligonucleotide probes from the support (col. 8, lines 36-39; col. 12, lines 63, 64; col. 16, lines 44-46; Fig. 3).); and

c) contacting said first and second oligonucleotides with a composition comprising at least a first and second target nucleic acid, whereby said first and second target nucleic acids hybridize with said first and second oligonucleotides whereby said target nucleic acids are detected (Beattie teaches contacting the oligonucleotide probes with a composition comprising at least two fragments of genomic DNA, which can be obtained by PCR, restriction fragmentation, etc. (col. 10, lines 1-67).

Regarding claims 5 and 31, Beattie teaches covalent attachment of the oligonucleotides to the substrate (col. 8, lines 30-36; col. 12, lines 60-62; col. 16, lines 39-42; Fig. 3).

Regarding claim 3, Beattie teaches labeled probes (col. 11, lines 5-7).

Regarding claim 4, Beattie teaches using different labels (col. 11, lines 55-62).

Regarding claims 6 and 9, Beattie teaches synthesis of oligonucleotides on the substrate (col. 8, lines 30-36; col. 12, lines 60-62; col. 16, lines 39-42; Fig. 3).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 2-10 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes (U.S. Patent No. 5,679,773; cited in the office action of August 13, 2002) and Beattie (U.S. Patent No. 6,156,502).

A) Since claims 28 and 29 are species of claims 27 and 30, only steps of claims 28 and 29 are discussed explicitly.

Regarding claims 27-30, Holmes teaches a method of synthesis and release of nucleic acids, the method comprising:

a) providing a substrate and a population of oligonucleotides, said population comprising at least first and second different oligonucleotides, respectively, said first and second oligonucleotides being immobilized to first and second beads, respectively, through first and second cleavable linkers, respectively, said first and second beads being distributed on said substrate (Holmes teaches providing a substrate and compounds, such as oligonucleotides, synthesized on solid supports (= substrate), which may contain wells. Compounds are synthesized on beads distributed on the surface of the support (Abstract; col. 5, lines 64-67; col. 6, lines 26-37; col. 19, lines 58-67; col. 20, lines 1-7; col. 22, lines 11-16). Holmes teaches preparation of high-density arrays of diverse oligonucleotides (col. 2, lines 1-7; col. 10, lines 15-25), therefore Holmes teaches at least first and second oligonucleotides.);

b) cleaving said first and second linkers, thereby releasing said first and second subpopulations from said first and second beads, thereby generating a pool of oligonucleotides comprising said first and second oligonucleotides (Holmes teaches cleaving the oligonucleotide probes from the support (col. 6, lines 36, 37; col. 12, lines 6-16). Since Holmes teaches multiple diverse oligonucleotides, cleavage generates a pool of oligonucleotides comprising first and second different oligonucleotides, anticipating this limitation.) ; and

c) contacting said first and second oligonucleotides with a composition comprising at least a first and second target nucleic acid, whereby said first and second target nucleic acids hybridize with said first and second oligonucleotides whereby said target nucleic acids are detected (Holmes teaches contacting the oligonucleotide array with a sample or using released oligomers in bioassays (col. 10, lines 18-21; col. 12, lines 15, 16). Holmes teaches using arrays for sequencing by hybridization (col. 1, lines 61-67).)

Regarding claim 2, Holmes teaches nucleic acids which are synthesized with DNA or RNA binding sequences which act as "receptors" for other nucleic acid sequences (col. 5, lines 64-66). Holmes does not specifically teach oligonucleotides with known sequences, but since they are synthesized to bind a specific sequence, their sequences must be known. Thus Holmes anticipates limitation of claim 2.

Regarding claim 3, Holmes teaches attaching labels to compounds synthesized on a substrate (col. 20, lines 33-67) and labeled beads attached to oligonucleotides (col. 10, lines 6-14).

Regarding claim 4, Holmes teaches labeled beads attached to oligonucleotides, where the beads are unique to each oligonucleotide or probe (col. 10, lines 6-14), anticipating the limitation of first and second oligonucleotides having different labels.

Regarding claims 5 and 31, Holmes teaches oligomers (e.g. oligonucleotides) attached to the solid support by covalent linkers, which are photochemically or chemically cleavable (col. 11, lines 23-67; col. 12, lines 6-16; col. 20, lines 7-32).

Regarding claims 6 and 9, Holmes teaches synthesis of oligonucleotides on a substrate (col. 6, lines 26-37; col. 22, lines 11-16).

Regarding claim 7, Holmes teaches substrate comprising discrete sites, such as wells, trenches, etc. (col. 6, lines 27-32).

Regarding claim 8, Holmes teaches beads distributed on a substrate and synthesis of oligomers on the beads (col. 6, lines 34-37; col. 9, lines 30-67; col. 10, lines 1-5).

Regarding claim 10, Holmes teaches synthesis of compounds by photolithography (col. 7, lines 23-40; col. 18, lines 1-67).

B) Holmes teaches oligonucleotide arrays, sequencing by hybridization and using cleaved oligonucleotides in bioassays, but does not specifically teach contacting the oligonucleotides with target nucleic acids.

C) Beattie teaches a method of oligonucleotide fingerprinting (ASOF), in which oligonucleotides cleaved from a solid support are contacted with a sample comprising target nucleic acids (Fig. 6; col. 8, lines 30-39; col. 12, lines 57-64). The target nucleic acids are contained in genomic DNA (col. 3, lines 14-27) or total RNA (col. 4, lines 14-16).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the assay of Beattie to use oligonucleotides cleaved from solid support of Holmes. The motivation to do so, provided by Beattie, would have been that the ASOF assay was used in polymorphic marker analysis, species identification and transcriptional profiling without the need for electrophoresis (Abstract).

9. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

The examiner will move to the new office in Alexandria on January 8, 2004. The new phone number in that office is (571) 272-0789. Gary Benzion will move to the new office on January 22, 2004. His new phone number is (571) 272-0782.

TS
November 25, 2003

TS


JEFFREY FREDMAN
PRIMARY EXAMINER